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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,311	12/21/2000	Nicole Suci-Foca	58332-B/JPW/AJM/DRM	9607

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08/11/2003

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EXAMINER

BELYAVSKIY, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 08/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/746,311

Applicant(s)

SUCIU-FOCA ET AL.

Examiner

Michail A Belyavskyi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-42 and 66-70 is/are pending in the application.
- 4a) Of the above claim(s) 27-37, 41 and 66-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-40, 42 and 70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 19.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 06/16/03 (Paper No. 18), is acknowledged.

Claims 27-42 and 66-70 are pending.

Claims 27-37, 41 and 66-69 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Claims 38-40, 42 and 70 are under consideration in the instant application.

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in US on 06/15/2000. It is noted, however, that applicant has not filed a certified copy of the US00/16594 application as required by 35 U.S.C. 119(b).

3. Formal drawings have been submitted on 06/16/03 which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability."

Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

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Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in ABANDONMENT of the application.

Applicant is reminded that changes in the Brief Description of the Drawings will be required in accordance with these changes.

In view of the amendment, filed 06/16/03 (Paper No. 18) the following rejection remains:

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 38-40, 42 and 70 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of generating a tolerogenic antigen presenting cell which comprises : a) contacting the APC with Ts, wherein Tc are CD8+Cd28- T cells and b) overexpressing mRNA which encodes an MIR in the said APC, wherein MIR is selected from the group recited in claim 39 does not reasonably provide enablement for a method of generating a tolerogenic antigen presenting cell which comprises overexpressing mRNA which encodes *any inhibitory* MIR in the APC. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim for the same reasons set forth in the previous Office Action, Paper N0: 17, mailed 03.11.03.

Applicant's arguments, filed 06/16/03 (Paper No. 18) have been fully considered, but have not been found convincing.

Applicant asserts that claim 38 was amended to recite mRNA which encodes an inhibitory monocytes inhibitory receptor and that the specification provides the support for written description requirement for a claimed genus of inhibitory monocytes inhibitory receptor .

Contrary to Applicants assertion , it is noted that the rejection under first paragraph of 35 U.S.C. 112 in the previous Office Action, Paper N0: 17, mailed 03.11.03 was enablement rejection not written description rejection.

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The specification only discloses that contacting the APC with Ts, wherein Tc are CD8+Cd28- T cells and b) overexpressing mRNA which encodes a specific MIR in the said APC, wherein MIR is selected from the group recited in claim 39 will result in generating a tolerogenic APC (see fifth series of experiments in particular).

The specification does not adequately teach how to effectively generate a tolerogenic APC using the method comprising overexpressing mRNA which encodes *any inhibitory* MIR in the APC. The specification does not teach how to extrapolate data obtained from *in vitro* studies , using CD8+Cd28- T cells and mRNA which encodes an MIR recited in claim 39 commensurate in scope with the claimed invention. Therefore, it is not clear that the skilled artisan could predict the efficacy of generating a tolerogenic APC using the method comprising overexpressing mRNA which encodes *any inhibitory* MIR in the APC. Moreover, Applicants own data indicated that while transcription of wide array of genes was suppressed in APC in response to CD8+Cd28- T cells stimulation , only a *specific* inhibitory MIR, such as one recited in claim 39 but not *any inhibitory* MIR were unregulated in said APC (see page 146, line 10-20 in particular). Applicant stressed that it is essential for the invention that this upregulated MIR will transmits negative inhibitory signal that is crucial for generating a tolerogenic APC as claimed (see page 146, lines 22-30 in particular).

The specification does not provide sufficient teaching as to how it can be assessed that generating a tolerogenic APC was achieved using the method comprising overexpressing mRNA which encodes *any inhibitory* MIR in the APC.

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed method of generating a tolerogenic antigen presenting cell which comprises overexpressing mRNA which encodes *any inhibitory* MIR in the said APC in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

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The following new ground of rejection are necessitated by the amendment filed 06/16/03 (Paper No. 18).

5. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 38-40, 42 and 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. It is improper to recite "inhibitory monocytes inhibitory receptor (MIR)" in claim 38. It is unclear if "MIR" abbreviation refers to the genus of monocytes inhibitory receptor or to a subgenus of only inhibitory receptors. Applicant acknowledge that there are two subsets of monocytes inhibitory receptors: one subset is inhibitory receptors and another subset is activating receptors (see page 8, Applicant's amendment, filed 06/16/03 Paper No. 18 in particular). It is suggested that said phrase be changed to "inhibitory MIR" for clarity.

8. It is improper to recite "inhibitory (MIR)" in claim 39. It is suggested that said phrase be changed to "inhibitory MIR" for clarity.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 38-40, 42 and 70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection.**

"Inhibitory monocytes inhibitory receptor" claimed in Claim 38 represent a departure from the specification and the claims as originally filed. Applicant acknowledge that there are two subgenus of monocytes inhibitory receptors: one is inhibitory monocytes inhibitory receptor and another is activating monocytes inhibitory receptor (see page 8, Applicant's amendment, filed 06/16/03 Paper No. 18 in particular). The passages pointed by the applicant do not provide a clear support for the subgenus of "inhibitory monocytes inhibitory receptor". The

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specification as originally field only disclosed 3 species of monocytes inhibitory receptor, that are also recited in claim 39. The specification and the claims as originally field only support a genus of "monocytes inhibitory receptor". See *In re Smith* 173 USPQ 679, where it was ruled that a genus may not support a subgenus even though there is a disclosed species within the subgenus.

11. No claim allowed


12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskiy, Ph.D.
Patent Examiner
Technology Center 1600
August 5, 2003


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